

CLAIMS

What I claim is:

- 5 1. A method of treating an allergy in a patient in need thereof, comprising administering to the patient a therapeutically effective amount of a chitin microparticle (CMP) preparation, wherein the CMP preparation is administered intranasally or by inhalation and the chitin microparticles have an average diameter of less than 10 $\mu$ m.
- 10 2. The method of claim 1, wherein the allergy is selected from the group comprising seasonal respiratory allergies; allergy to aeroallergens; allergy treatable by reducing serum IgE and eosinophilia; asthma; eczema; food allergy; dermatitis; or the treatment of allergy by allergic desensitisation.
- 15 3. The method of claim 2, wherein the aeroallergen is selected from the group comprising house mite dust, fungal spores, grass pollens, tree pollens or animal danders.
4. The method of claim 2 wherein the dermatitis is atopic dermatitis.
- 20 5. The method of claim 1, wherein the chitin microparticle preparation is for allergic desensitisation and further comprises an allergen.
6. The method of claim 5, wherein the allergen is a food allergen.
- 25 7. The method of claim 6, wherein the food allergen is found in milk, wheat, gluten, eggs, nuts or shellfish.
8. The method of claim 1, wherein the patient is a non-human animal.
- 30 9. The method of claim 8, wherein the non-human animal is a horse and the allergy is asthma or is associated with recurrent lung infection.

10. A method of treating a condition in a patient in need thereof, wherein the condition would benefit from the up-regulation of the cell-mediated immune system, the method comprising administering to the patient a therapeutically effective amount of a chitin microparticle (CMP) preparation, wherein the CMP preparation is administered intranasally or by inhalation and the chitin microparticles have an average diameter of less than 10µm.

11. The method of claim 10, wherein the condition that would benefit from the up-regulation of the cell-mediated immune system is a bacterial infection, a fungal infection or a viral infection.

12. The method of claim 11, wherein the bacterial, fungal or viral infection is an ear, nose, throat or lung infection.

13. The method of claim 10, wherein the patient is at risk of developing an infection.

14. The method of claim 13, wherein the patient at risk of developing an infection is an elderly person, a premature baby, an infant, a transplantation patient, an immunosuppressed patient, a chemotherapy patient, a hospital patient at risk of opportunistic infection, a patient on a ventilator, a cystic fibrosis patient or a patient with AIDS.

15. The method of claim 11, wherein the condition is a bacterial infection by *Pseudomonas aeruginosa*, a *Streptococcus* species, *Haemophilus influenza*, *Klebsiella pneumoniae*, *Yersinia enteocolitica*, *Salmonella*, *Listeria*, a *Mycobacteria* species or a parasitic infection.

16. The method of claim 15, wherein the *Streptococcus* species is *Streptococcus pneumoniae*, *Streptococcus pyogenes* or *Streptococcus agalactiae*.

17. The method of claim 15, wherein the *Mycobacterial* species is *Mycobacterium tuberculosis* or *Mycobacterium leprae*.

18. The method of claim 15, wherein the parasitic infection is an infection by a *Leishmania* species or a *Schistosoma* species.

19. The method of claim 11, wherein the condition is bacterial pneumonia, ventilator-associated pneumonia or a cystic fibrosis associated infection.

20. The method of claim 11, wherein the condition is Otitis media.

21. The method of claim 11, wherein the fungal infection is invasive pulmonary aspergillosis, invasive pulmonary candidiasis, *Pneumocystis carinii* pneumonia, or a *Coccidioides* or *Cryptococcus*.

22. The method of claim 11, wherein the condition is a pulmonary viral infection.

23. The method of claim 11, wherein the viral infection is caused by infection by respiratory syncytial virus bronchiolitis, influenza virus, rhino virus or human immunodeficiency virus (HIV).

24. A method of treating a condition in a patient in need thereof, wherein the condition is treatable by up-regulation of the activity of NK cells and/or secretion of IFN- $\gamma$  by cells of the immune system, the method comprising administering to the patient a therapeutically effective amount of a chitin microparticle (CMP) preparation, wherein the CMP preparation is administered intranasally or by inhalation and the chitin microparticles have an average diameter of less than 10 $\mu$ m.

25. The method of claim 24, wherein the condition is cancer.

26. The method of claim 24, wherein the condition is lung cancer, lung carcinoma or nasal-pharyngeal carcinoma.

27. The method of claim 24, wherein the condition is a chronic lung disorder.

28. The method of any one of claims 1, 10 or 24, wherein the CMP preparation is administered prophylactically.

5 29. The method of any one of claims 1, 10 or 24, wherein the chitin microparticles have an average diameter of less 5 $\mu$ m.

30. The method of any one of claims 1, 10 or 24, wherein the chitin microparticles have an average diameter of at least 1 $\mu$ m.

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31. The method of any one of claims 1, 10 or 24, wherein the chitin microparticles are derived from the exoskeletons of crab, shrimp, lobster, cuttlefish, insects or fungi.

15 32. The method of any one of claims 1, 10 or 24, wherein the chitin microparticles are obtainable by sonicating or milling purified chitin.

33. The method of any one of claims 1, 10 or 24, wherein the chitin microparticles are obtainable by coating carrier particles with *N*-Acetyl-D-Glucosamine, chitin or a fragment thereof.

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34. The method of any one of claims 1, 10 or 24, wherein the CMP preparation is administered to a patient in a therapeutically effective amount of between 0.01 and 100mg of active compound per kg of body weight.

25 35. The method of any one of claims 1, 10 or 24, wherein the CMP preparation is administered to humans.

36. The method of any one of claims 1, 10 or 24, wherein the chitin microparticle preparation comprises one or more of a pharmaceutically acceptable excipient, a carrier, a propellant, a buffer, a stabiliser, an isotonicizing agent, a preservative or an antioxidant.

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37. A delivery device for the administration of a chitin microparticle (CMP) composition:
- a) a reservoir of chitin microparticles having an average diameter of less than 10 $\mu$ m;
  - b) a delivery orifice adapted to locate in a patient's mouth or nose; and
  - c) a valve between the reservoir and the delivery orifice such that the valve can be

5 operated to control delivery of the chitin microparticles.

38. A composition comprising a chitin microparticle composition and an allergen, wherein the chitin microparticles have a diameter of less than 10 $\mu$ m.

- 10 39. The composition of claim 38, wherein the allergen is a food allergen.

40. The composition of claim 39, wherein the food allergen is an allergen found in milk, wheat, gluten or eggs.

- 15 41. A kit comprising:

- (a) a chitin microparticle composition wherein the chitin microparticles have a diameter of less than 10 $\mu$ m; and
  - (b) an allergen;
- for simultaneous or sequential administration to a patient.

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42. A method for up-regulating the cell-mediated immune system comprising administering to a patient a therapeutically effective amount of a chitin microparticle (CMP) preparation, wherein the CMP preparation is administered intranasally or by inhalation and the chitin microparticles have an average diameter of less than 10 $\mu$ m.

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43. A method for up-regulating the activity of NK cells and/or secretion of IFN- $\gamma$  by cells of the immune system, comprising administering to a patient a therapeutically effective amount of a chitin microparticle (CMP) preparation, wherein the CMP preparation is administered intranasally or by inhalation and the chitin microparticles have an average diameter of less than

30 10 $\mu$ m.